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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/500,911	07/08/2004	Masakuni Noda	3011 USOP	7125

23115 7590 12/12/2006

TAKEDA PHARMACEUTICALS NORTH AMERICA, INC
INTELLECTUAL PROPERTY DEPARTMENT
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EXAMINER	
SULLIVAN, DANIEL M	
ART UNIT	**PAPER NUMBER**
1636	

DATE MAILED: 12/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/500,911	NODA ET AL.	
	Examiner	Art Unit	
	Daniel M. Sullivan	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-37 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-37 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☒ Other: See Continuation Sheet.

Continuation of Attachment(s) 6). Other: Sequence alignment 20061004_143703_us-10-500-911-1.rag.

DETAILED ACTION

Claims 1-37 are pending.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-11, drawn to a method of screening for a prophylactic and therapeutic substance comprising using a protein comprising SEQ ID NO: 1.

Group II, claim(s) 14-20, drawn to a method of screening for a prophylactic and therapeutic substance comprising using a nucleic acid encoding a protein comprising SEQ ID NO: 1.

Group III, claim(s) 12, 13, 21, 22, 32 and 33, drawn to a compound that might be obtained by a method of screening for a prophylactic or therapeutic substance using a protein comprising SEQ ID NO: 1 or a polynucleotide comprising a base sequence encoding SEQ ID NO: 1.

Group IV, claim(s) 23, 24 and 26, drawn to an antibody against a protein represented by SEQ ID NO: 1.

Group V, claim(s) 25 and 27, drawn to a polynucleotide having a complementary base sequence to the base sequence encoding SEQ ID NO:1.

Group VI, claim(s) 28-31, drawn to a nucleic acid comprising SEQ ID NO: 5 or 6.

Group VII, claim(s) 34 and 35, drawn to a method of prophylaxis or treatment comprising administering a suppressor of Egr-1.

Group VIII, claim(s) 36 and 37, drawn to the use of a suppressor of Egr-1 in the manufacture of a medicament.

The inventions listed as Groups I-VIII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

37 CFR 1.475(b) states:

"An international or a national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn only to one of the following combinations of categories:

(1) A product and a process specially adapted for the manufacture of said product; or
(2) A product and process of use of said product; or
(3) A product, a process specially adapted for the manufacture of the said product, and a use of the said product; or
(4) A process and an apparatus or means specifically adapted for the manufacture of the said product; or
(5) A product, a process specially adapted for the manufacture of the said product, and an apparatus or means specifically designed for carrying out the said process."

Furthermore, according to PCT Rule 13.2, unity of invention exists only when there is a shared same or corresponding special technical feature among the claimed inventions. The "Instructions Concerning Unity of Invention" (MPEP, Administrative Instructions Under the PCT, Annex B, Part 1(b)) state, "The expression 'special technical features' is defined in Rule 13.2 as meaning those technical features that define a contribution which each of the inventions, considered as a whole, makes over the prior art."

Still further, according to PCT Rule 13.2, unity of invention exists only when there is a shared same or corresponding special technical feature among the claimed inventions. The "Instructions Concerning Unity of Invention" (MPEP, Administrative Instructions Under the PCT, Annex B, Part 1(b)) state, "The expression 'special technical features' is defined in Rule 13.2 as meaning those technical features that define a contribution which each of the inventions, considered as a whole, makes over the prior art." Thus, unity of invention exists only when the shared same or corresponding technical feature is a contribution over the art.

The instant claims are directed to inhibitors of Egr-1 (Group III), antibodies against the Egr-1 protein (Group IV), antisense nucleic acids complementary to nucleic acids encoding the Egr-1 protein (Group V), nucleic acids encoding Egr-1 binding sites (Group VI) and methods of making and using the various products.

First, each of the antisense nucleic acids, binding site nucleic acids, and antibodies of the product Groups are directed to a compounds having structurally and functionally different characteristics, which structural and functional characteristics define a distinct special technical feature not shared by the other groups.

With regard to the process claims, each of the processes of Groups I, II, VII and VIII utilize distinct reagents, which are not used in the other Groups or comprise process steps not comprised by the other Groups. Specifically, Group I is directed to a process comprising the process steps of a pharmaceutical screening method, wherein the method utilizes a polypeptide comprising SEQ ID NO: 1. None of the other process Groups comprise the combination of elements

comprised by the method of Group I. Likewise, the process of Group is directed to a process comprising the process steps of a pharmaceutical screening method, wherein the method utilizes a nucleic acid encoding a polypeptide comprising SEQ ID NO: 1; Group VII is directed to a process comprising the step of administering a therapeutic; and Group VIII is directed to a process comprising the step of manufacturing a medicament. Thus, each of the process Groups comprise elements not comprised by the processes of the other Groups, which define a unique special technical feature of the respective Groups.

With regard to the Groups related a product and methods of using said product, as discussed above, under the rules for unity of invention Applicant may be entitled to examination of an independent claim for a given product, an independent claim for a process specially adapted for the manufacture of the said product, and an independent claim for a use of the said product together in a single application. However, regarding unity of invention among distinct categories of invention, MPEP 1850 III. A. states, "A single general inventive concept must link the claims in the various categories..." In the instant case, the shared technical feature common to the product and process claims is not a contribution over the art (i.e., not a general inventive concept).

Specifically, none of the products made by or used in the process Groups represent a contribution over the art. Groups I and II are directed to methods of producing prophylactic and therapeutic substances for diseases associated with the polypeptide encoded by SEQ ID NO: 1. The prophylactic and therapeutic compounds of the claims are anticipated by the antisense molecules disclosed in Monia et al. US Patent No. 6,008,048, which are targeted to nucleic acid molecules encoding SEQ ID NO: 1 (see especially the "SUMMARY OF THE INVENTION" in column 2, SEQ ID NO: 1 of Monia et al. and the attached sequence alignment). These sequences also read on the suppressor used in the therapeutic method of Group VII and the method of making a medicament of Group VIII. Thus, the products and methods of the instant claims lack a unifying technical feature that represents a contribution over the prior art. Therefore, there is no special technical feature that unites the product and process claims.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder

in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel M Sullivan whose telephone number is 571-272-0779. The examiner can normally be reached on Monday through Friday 6:30-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on 571-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) (http://pair-direct.uspto.gov) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's

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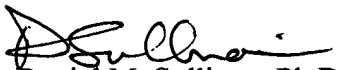
For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.



Daniel M. Sullivan, Ph.D.
Primary Examiner
Art Unit 1636

20061004_143703_us-10-500-911-1.rag

<!--StartFragment-->RESULT 11
AAY51116
ID AAY51116 standard; protein; 543 AA.
XX
AC AAY51116;
XX
DT 24-MAR-2000 (first entry)
XX
DE Human EGR-1 protein.
XX
KW EGR-1; early growth response 1; antisense; inhibition; human; primer;
KW anti-inflammatory; cytostatic; antiviral; detection; diagnosis;
KW viral infection; inflammation; tumor.
XX
OS Homo sapiens.
XX
PN US6008048-A.
XX
PD 28-DEC-1999.
XX
PF 04-DEC-1998; 98US-00205921.
XX
PR 04-DEC-1998; 98US-00205921.
XX
PA (ISIS-) ISIS PHARM INC.
XX
PI Monia BP, Cowsert LM;
XX
DR WPI; 2000-096375/08.
DR N-PSDB; AAZ44123.
XX
PT Antisense oligonucleotides that inhibit expression of human early growth
PT response-1, useful for diagnosis, treatment and prevention of tumors,
PT inflammation and infection.
XX
PS Example 13; Col 43-46; 31pp; English.
XX
CC This invention describes novel antisense oligonucleotides (I) capable of
CC inhibiting expression of human EGR-1 (early growth response-1). The
CC products of the invention have anti-inflammatory, cytostatic and
CC antiviral activity. (I) was tested for its effects on EGR-1 mRNA levels
CC by real-time polymerase chain reaction (PCR), results indicated that 60%
CC inhibition was achieved. When (I) was modified by 2'-O-methoxyethyl
CC substitution of the first 4 and last 4 residues, and by replacing any C
CC in these flanking regions with 5-methyl-C, the degree of inhibition was
CC increased to 71%. (I) is used to inhibit expression of EGR-1 in cells and
CC tissues in vitro, for research or diagnosis, e.g. detecting EGR-1
CC encoding nucleic acid. (I) may also be used to treat or prevent EGR-1-
CC associated diseases, particularly viral infections, inflammation and
CC tumors. This sequence represents the human EGR-1 protein which is
CC inhibited by the antisense oligonucleotides represented in AAZ44124-
CC Z44169
XX
SQ Sequence 543 AA;

  Query Match   100.0%; Score 674; DB 3; Length 543;
  Best Local Similarity   100.0%; Pred. No. 4.6e-69;
  Matches 123; Conservative   0; Mismatches   0; Indels   0; Gaps   0;

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Qy          1 YQSQLIKPSRMRKYPNRPSKTPPHERPYACPVESCDRRFSRSDELTRHIRIHTGQKPFQC 60
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        311 YQSQLIKPSRMRKYPNRPSKTPPHERPYACPVESCDRRFSRSDELTRHIRIHTGQKPFQC 370

Qy         61 RICMRNFSRSDHLTTHIRTHTGEKPFACDICGRKFARSDERKRHTKIHLRQKDKKADKSV 120
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        371 RICMRNFSRSDHLTTHIRTHTGEKPFACDICGRKFARSDERKRHTKIHLRQKDKKADKSV 430

Qy        121 VAS 123
              |||
Db        431 VAS 433
```

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